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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,770	07/22/2003	Michael A. Centanni	ST8011US	6775
22203	7590	07/25/2006	EXAMINER	
KUSNER & JAFFE HIGHLAND PLACE SUITE 310 6151 WILSON MILLS ROAD HIGHLAND HEIGHTS, OH 44143			JASTRZAB, KRISANNE MARIE	
			ART UNIT	PAPER NUMBER
			1744	

DATE MAILED: 07/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/624,770

Applicant(s)

CENTANNI, MICHAEL A.

Examiner

Krisanne Jastrzab

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-16, 18, 28-34 and 36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-16, 18, 28-34 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10-11, 13-14, 18, 28-29, 31-32 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Priest U.S. patent No. 5,789,175 in view of Esch et al., U.S. patent No. 4,205,043.

Priest teaches a method and apparatus for monitoring the progress of a vapor hydrogen peroxide sterilization process. The sealed enclosure containing articles to be treated, includes means for intermittently exposing an annular chemical indicator strip to the interior atmosphere of the enclosure and thereafter inspecting the strip for color changes indicative of the presence and concentration of hydrogen peroxide. The strip is stepwise advanced upon each exposure. The strip carrying the indicator chemistry

can be either paper or a polymer. See column 3, lines 64-68, column 4, lines 33-68, and column 5, lines 1-12.

Esch et al., teaches the known and expected use of an indicator assembly having a plurality of indicator discs located thereon each responsive to a different exposure time and concentration of the agent being monitored. This construction allows for an inexpensive, yet easily read indicator providing a profile of activity of the agent being monitored. See column 3, lines 5-65.

It would have been obvious to one of ordinary skill in the art to employ an indicator assembly as taught in Esh et al., in the system of Priest because it would provide an inexpensive, yet accurate means of tracking the concentration and exposure time of the sterilization process in a staged, profiled manner.

Claims 10-11, 13-14, 16, 28-29, 31-32, 34 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu U.S. patent No. 6,087,089 in view of Esch et al., U.S. patent No. 4,205,043.

Wu teaches measurement of peroxide concentrations in a sterilization field using a chemical indicator strip. The strip can be formed with either paper or a polymer and carries an indicating composition that changes color upon exposure to a sterilant such as hydrogen peroxide. The indicating chemistry taught in Wu includes iodides, thiosulfates and starches.

Esch et al., is applied as set forth above.

It would have been obvious to one of ordinary skill in the art to employ the plural indicator configuration as set forth in Esch et al., to in the sterilization system of Wu

because it would provide an inexpensive, yet accurate means of tracking the concentration and exposure time of the sterilization process in a staged, profiled manner.

Claims 12, 15, 30 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu and Esch et al., as applied to claims 10-11, 13-14, 16, 28-29, 31-32, 34 and 36 above, and further in view of either Thornton et al., U.S. patent No. 5,770,150 or Kirckof U.S. patent No. 6,488,890 B1.

Both Thornton et al., and Kirckof teach the conventionality of the use of an iodide, thiosulfate and starch in the chemistry for indicating the presence of hydrogen peroxide. It would have been well within the purview of one of ordinary skill in the art to utilize a conventionally recognized indicating composition such as one including an iodide, thiosulfate and starch as taught in both Thornton et al., and Kirckof, because it would provide known reactive color changes indicative of the presence of hydrogen peroxide.

Response to Arguments

Applicant's arguments filed 5/12/2006 have been fully considered but they are not persuasive.

Applicant argues that Esch et al., is not analogous art to those references teaching sterilization indicators, however, the Examiner would disagree and maintain that all of the indicators of the applied prior art are indicative of harsh environments, and indicative of the presence, exposure time and concentration of chemicals. All of the applied references teach chemical indicator strips. In fact, the Examiner would point out

that Table 1 of Esch et al., found in column 3, clearly cited well known sterilants as chemicals capable of being monitored by the indicator, namely, chlorine dioxide, chlorine and ethylene oxide. The Examiner would further note that Wu clearly equates the sterilants of chlorine and peroxide. Thus the requirements of *prima facie*, are clearly and properly met in the rejections above.

Applicant further requests clarification of the part that Moses et al., provides in the rejection of the instant claims. The Examiner has withdrawn the recitation of Moses et al., from the rejection as it is no longer pertinent and was inadvertently included in the last rejection.

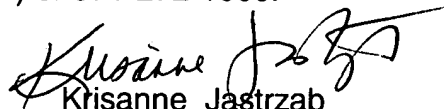
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krisanne Jastrzab whose telephone number is 571-272-1279. The examiner can normally be reached on Mon.-Thurs. 6:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1744

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Krisanne Jastrzab
Primary Examiner
Art Unit 1744

July 21, 2006